(viii) Has the filter chambers designed to allow in-place decontamination before the filters are removed and to facilitate certification testing.

(ix) Contains prefilters and HEPA filters in the air supply system to protect the supply air system should air pressures become unbalanced.

(x) Exhausts the HEPA-filtered air from Class I or II biological safety cabinets directly into the laboratory or to the exterior of the building. If the HEPA-filtered exhaust from these cabinets is recirculated, the cabinets are tested and certified every 6 months. If the filtered cabinet exhaust is discharged through the building exhaust system, it will be connected to this system in a manner (for example, thimble unit connection) that avoids any interference with the air balance of the cabinets or the building exhaust system.

(xi) Passes the treated exhaust air from Class III biological safety cabinets through two sets of HEPA filters in series to the exterior of the facility through the laboratory exhaust air system.

(14) Windows (if present) sealed shut and breakage resistant.

(15) Has a double-doored autoclave for decontaminating materials passing out of the facility. The autoclave door that opens to the area external to the facility is sealed to the outer wall and automatically controlled so that it can only be opened after the autoclave sterilization cycle has been completed.

(16) Has a pass-through dunk tank, fumigation chamber, or an equivalent decontamination method for materials and equipment that cannot be autoclaved.

(17) Has central vacuum systems (if present) that—

(i) Do not serve areas outside the facility.

(ii) Have an in-line HEPA filter placed as near as practicable to each use point or service cock.

(iii) Have filters designed to allow in-place decontamination and replacement.

(18) Liquid and gas services to the facility provided with protective devices that prevent backflow.

(b) *Additional requirements for personal positive pressure suit areas.* If personal positive pressure suits are worn in lieu of using Class III biological safety cabinets for containment, a special suit area will be provided. The suit area will provide the following, in addition to the requirements stated in § 627.46(a):

(1) An exhaust system dedicated to that area that provides filtration by two sets of HEPA filters installed in series. This system will be backed up by a duplicate filtration unit, exhaust fan, and an automatically starting emergency power source. The ventilation system will maintain the suit area under negative pressure relative to the surrounding areas.

(2) An entry area consisting of an airlock fitted with airtight doors.

(3) A chemical shower to decontaminate the surface of the personal positive pressure suit upon exit.

(4) An air supply and distribution system to support the life support system of the personal positive pressure suits.

(5) Emergency lighting and communications systems.

(6) Sealed penetrations into the internal shell of the area.

(7) A double-doored autoclave to decontaminate waste materials to be removed from the suit area.

(c) *Additional laboratory requirements.* In addition to those given in § 627.45, if water fountains are provided, they will be foot operated and located in the facility corridors outside the laboratory.

(d) *Additional animal facility requirements.* In addition to those requirements given in § 627.45, all animal facility external doors will be self-locking.

§ 627.47 Large-scale facilities.

The following requirements apply to facilities in which an individual culture of viable etiologic agents exceed 10 liters:

(a) *BL–1 LS.* In addition to the laboratory requirements stated § 627.43(a), the exhaust gases removed from a closed system or other primary containment equipment shall be treated by filters which have efficiencies equivalent to HEPA filters or by other equivalent procedures (for example, incineration) to minimize the release of viable organisms.

(b) *BL–2 LS.* In addition to the requirements stated in §§ 627.44(a) and 627.47(a), these facilities will have—

(1) Rotating seals and other mechanical devices directly associated with a closed system used to contain viable organisms shall be designed to prevent leakage or shall be fully enclosed in ventilated housings that are exhausted through filters which have efficiencies equivalent to HEPA filters or through equivalent treatment devices.

(2) A closed system used to propagate and grow viable organisms shall include monitoring or sensing devices that monitor the integrity of containment during operations.

(3) Closed systems used for the propagation and growth of viable organisms shall be tested operationally for integrity of the containment features. The containment will be rechecked following modification or replacement of essential containment features. Procedures and methods used in the testing shall be appropriate for the equipment design and for recovery and demonstration of the test organism. Records of tests and results shall be maintained on file.

(c) *BL–3 LS.* The requirements stated in §§ 627.45 and 627.57(b) apply, and all closed systems and other primary containment equipment used in handling cultures of viable organisms shall be located within a controlled area which meets the requirements of a BL–3 facility plus the following requirements:

(1) All utilities and service or process piping or wiring entering the controlled area shall be protected against contamination.

(2) A shower facility shall be provided. This facility shall be located near the controlled area.

(3) The controlled area shall be designed to preclude release of culture fluids outside in the event of an accidental spill or release from the closed systems or other primary containment equipment.

(4) The controlled area shall have a ventilation system capable of controlling air movement. The movement of air shall be from areas of lower contamination potential to areas of higher contamination potential. If the ventilation system provides positive pressure supply air, the system shall operate so as to prevent the reversal of air movement or shall be equipped with an alarm that would be actuated if reversal in the direction of air movement were to occur. The exhaust air from the controlled area shall not be recirculated to other areas of the facility. The exhaust air from the controlled area may be discharged to the outdoors after filtration or other means of effectively reducing an accidental aerosol burden, and dispersed clear of occupied buildings and air intakes.

§ 627.48 Toxins.

General requirements for all facilities in which toxins are used are as follows. Such facilities will—

(a) Have a ventilation system that provides three to six air changes per hour, and that provides a directional airflow inward relative to the access halls.

(b) Have a sink for handwashing.

(c) Have an eyewash available.

(d) Have bench tops that are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

(e) Have furniture, furnishings, and surfaces that are sturdy and designed to be easily cleaned.

(f) Be arranged so that items are accessible for cleaning.

(g) Have a quick-drench shower available within the facility.

(h) A fume hood, biological safety cabinet, glove box, or equivalent engineering control equipped with HEPA filters and with charcoal filters if volatile materials are being used.

Subpart H—Engineering Controls

§ 627.49 Introduction.

As required by the OSHA and recommended by the American Industrial Hygiene Association (AIHA) and the CDC, engineering controls and proper microbiological techniques are the primary means of protecting personnel who work with potentially hazardous biological materials. In situations of potentially higher hazard, these engineering controls are supplemented by personal protective clothing and equipment. Thus, the engineering controls discussed in this chapter will be the